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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/835,964	02/20/92	COATES J	IAF-14

HM22/0812

MILLEN, WHITE, ZELANO &
BRANIGAN, P.C.
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BLVD., SUITE 1400
ARLINGTON VA 22201

EXAMINER	
KRASS, F	
ART UNIT	**PAPER NUMBER**
1614	46

DATE MAILED: 08/12/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 07/835,964	Applicant(s) Coates et al.
	Examiner Frederick Krass	Group Art Unit 1614

☒ Responsive to communication(s) filed on *Jun 25, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *25-29, 31-34, 37-39, and 43-58* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *25-29, 31-34, 37-39, and 43-58* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Formal Issues

1) The third line of claim 25 contains an obvious spelling error.

2) Claim 25, seventh line, the construction of the wording is awkward; the examiner recommends deleting the word "is" as it appears before "present".

Indefiniteness Rejection

Claims 48-52, 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not seen how claim 48 limits claim 43 from which it depends, since claim 43 already recites the active agent specified in claim 48.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-29, 31-34, 37-39 and 43-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al (USP 5,539,116) or Belleau et al (USP 5,047,407), each reference being considered individually and separately.

Liotta et al disclose the use of the instant compounds to treat HIV. See specifically claim 1. Belleau et al disclose substantially the same; see specifically column 5, lines 28-42. Neither reference specifically discloses the incorporation of an additional antiviral agent.

It is generally obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See, only as exemplary, the dicta of *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. See, again only as exemplary, the dicta of *In re Crockett* 126 USPQ 186, 188. Since antiviral agents such as AZT are of course well-known, it would have been obvious to have combined such an agent or agents with those disclosed in Liotta et al or Belleau et al, motivated by the reasonable expectation of providing two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, consonant with the reasoning of the dicta of the above-cited cases. The selection and optimization of their individual and relative dosages is routine in the pharmaceutical art, and as such would have been obvious to anyone of ordinary skill.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-29, 31-34, 37-39 and 43-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30, 31 and 33-74 of copending Application No. 08/460,854. Although the conflicting claims are not identical, they are not patentably distinct from each other because the lowered cytotoxicity emphasized in the conflicting claims is an inherent feature of the instantly claimed methods, since the very same active agent is being used in both instances.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications regarding the substantive aspects of the communication (the action *per se*, questions regarding patentability, etc) from the examiner should be directed to Frederick Krass whose telephone number is (703) 308-4335. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

The examiner generally returns his phone calls in a very prompt manner. If attempts to reach the examiner by telephone are unsuccessful (allowing for a few days in case the examiner is on sick leave), the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Frederick Krass
Primary Examiner
Art Unit 1614